



A: 59807(1@5B011.DOC)

Appellants further request that the Oral Hearing in the present case be scheduled at the same time as those that will be set in connection with the appeal in USSN 08/112,245. The '245 case has essentially the same specification as the present case, but is entitled to a much earlier filing date for its claims. The '245 case is directed generically to fertile, transgenic corn, as well as to transgenic species bearing certain specified genes. It is the Appellants' position in the '245 case that one of skill in the art was not enabled to prepare fertile, transgenic corn prior to the making of that invention. However, the '245 claims are directed to related subject matter, and the prior art reference of Goldman *et al.* is common to both the '245 appeal and the present appeal. Furthermore, the '245 claims are directed to subject matter prior in time to that of the present case, in a "genus-species" relationship. The '245 case includes subject matter directed generically to 'fertile, transgenic corn', whereas the present case includes species claims to corn bearing individual transgenes.

Since the cases are related, and the claims are directed to related subject matter, in a "genus - species" relationship, Appellants submit that consideration of both cases at Oral Hearing by the same panel would provide not only for judicial economy, but would also avoid inconsistent holdings.

Respectfully submitted,

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Re: SN 08/113,561; "METHODS AND COMPOSITIONS FOR THE
PRODUCTION OF STABLY TRANSFORMED, FERTILE MONOCOT
PLANTS AND CELLS THEREOF" -- Thomas R. Adams et al.

Sir:

Enclosed for filing in the above-referenced patent application is:

- 1.) An Appellants' Reply to Examiner's Answer with Appendix A (Original and two copies);
- 2.) A Request for Oral Hearing; and Request to Consolidate Oral Hearing with that of Related Case USSN 08/112,245;
- 3.) An Amendment under 37 C.F.R. § 1.16;
- 4.) A check for \$250.00 to cover the filing fee for the Request for Oral Hearing; and
- 5.) A return postcard to acknowledge receipt of these materials. Please date stamp and mail this postcard.

Should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should there be an

ARNOLD, WHITE & DURKEE

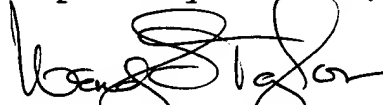
Assistant Commissioner for Patents

May 7, 1996

Page 2

overpayment, the Commissioner is authorized to deduct or credit said fees from Arnold, White & Durkee Deposit Account No. 01-2508/DEKM:055:PAR.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Wendy L. Taylor", written over a horizontal line.

Wendy L. Taylor for

David L. Parker

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Enclosures



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UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

#36
M.G.J.
5/15/96

In re Application of:
Adams *et al.*

Serial No.: 07/113,561

Filed: August 25, 1993

For: METHODS AND COMPOSITIONS
FOR THE PRODUCTION OF
STABLY TRANSFORMED,
FERTILE MONOCOT PLANTS
AND CELLS THEREOF

Do not file
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§ Group Art Unit: 1804
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§ Examiner: G. Benzion
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§ Atty. Dkt.: DEKM:055/PAR
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David L. Parker

APPELLANTS' REPLY TO EXAMINER'S ANSWER

Assistant Commissioner for Patents
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Sir:

Appellants provide the following Reply to the Examiner's Answer, including a reply to the
positions taken in the pending § 103 rejections and a response to the new ground of rejection under 35
U.S.C. § 112, second paragraph.

A. The Section 103 Rejections

1. Goldman et al., U.S. Patent 5,187,073

The Answer notes that the appeal in the related '844 case (Adams et al.) has been resolved, and a notice of allowance issued. In the '844 appeal, claims to fertile, transgenic corn bearing a transgenic *bar* gene (tolerance to the herbicide bialophos) were both rejected over the Goldman '073 patent and Lundquist. The Goldman patent is not relevant here for the same reasons as in the '844 appeal -- it is not enabling for any fertile, transgenic corn of any kind, much less the particular transgenics of the present invention (see Exhibit M to main Brief). It is agreed that the Lundquist reference is fully enabling for fertile, transgenic corn in general, and enabling for the particular transgenic corn species that it discloses. Thus, the pending rejection over Lundquist is determinative of this appeal.

Appellants continue to contest the relevancy of Goldman in the present Appeal, and refer the Board to the argument set forth in Exhibit M. An appeal in related case serial number 08/112,245 (Lundquist II) is now being undertaken. In that appeal, Goldman is the principal art reference, and the Board will be asked to consider, among other things, the non-enablement of the Goldman reference. Due to the much earlier priority date of Lundquist II, it is contemplated that the enablement issue with respect to Goldman will be decided prior to the decision in the present Appeal. If not, Appellants intend to present Oral Argument based upon Exhibit M to address the issue of Goldman's enablement.

2. Lundquist et al., U.S. Patent 5,484,956

Appellants initially observe that the obviousness-type double patenting rejection over Lundquist was withdrawn, but the § 103 rejection maintained. In withdrawing the obviousness-type double

patenting rejection, the Answer observed that the now issued Lundquist claims are directed to fertile, transgenic maize expressing *Bt* endotoxin, and concludes that the appealed claims are not obvious over transgenic maize expressing *Bt* endotoxin. Appellants submit that since the present claims are non-obviousness over transgenic corn expressing *Bt* endotoxin, they must also be patentable over the admittedly distinct transgenic species set forth in Lundquist.

In the § 103 rejection, the Answer's position is that the particular genes specified in each of the appealed claims are known to function to provide a trait in plants other than corn. Since, it is alleged, the genes are known to provide a trait in some other plant like tobacco, corn plants genetically engineered to incorporate such a gene are *prima facie* obvious. The motivation to introduce these genes into corn is said to arise out of Lundquist, which sets forth several traits and exemplary genes that one might introduce into corn. There is no allegation, nor can there be one, that the genes of the present claims and those disclosed in Lundquist are "structurally obvious" variants.

Lundquist teaches fertile, transgenic corn generically, as well as a variety of particular transgenic corn expressing a particular trait or bearing a particular gene. Exemplary traits and genes disclosed by Lundquist are recited in the Answer at the bottom of page 7. Yet, Lundquist, alone or in combination with secondary references, does not teach or suggest transgenic corn bearing the specific genes set forth in the appealed claims, provides no motivation for preparing transgenic corn bearing these particular genes and contains no evidence that that such an undertaking would be successful. *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

The Answers' Characterization of the Prior Art is Overly Broad

Only a few secondary references are mentioned in the Answer, and these only in connection with the rejection over Goldman. The Answer places reliance on what it terms Appellants' "admissions" as to the scope and content of the prior art. Appellants in no way concede that all of the gene elements set forth in the appealed claims have been expressed in plants other than corn, and/or successfully used in the prior art to achieve a desired transgenic trait. Many of the genes or genetic elements have only been studied by genetic engineering, and not expressed transgenically in a plant. Several of the specified genes have been expressed in plants, but only in plants such as *Arabidopsis* or tobacco quite distinct from corn.

In its Brief, Appellants properly maintained the right to have the claims considered separately. 37 C.F.R. § 1.192(c)(5). Each of claims 47 and 60-67 were separately argued, and the exemplary art considered by Appellants was distinct from claim to claim. Yet, the Answer does not directly address each of the rejections individually. The Board is requested to consider each claim in light of the patentability of the particular gene species set forth in that claim, as argued in Appellants' main Brief.

Overview of the Exemplary Art

An overview of the exemplary references set forth as Brief Exhibits D-L and argued with respect to claims 47 and 60-67, shows the following general categories:

1 Less than one-half of the genes listed in the claims have been expressed transgenically in a plant. These were limited to transgenic expression in a dicot such as tobacco or *Arabidopsis*.

2. Many genes have been isolated from other organisms and plants. These genes have been genetically engineered in recombinant bacterial systems and not genetically engineered in plants.

3. Still many other of the specified genes have been described in the art, for example in various plants such as tobacco, rice, corn, and soybean, but not genetically engineered into a transgenic plant.

Genes Previously Expressed in Dicots Do Not Render Transgenic Corn Species Obvious

As noted, some of the claimed transgenic corn species bear genetic elements previously expressed transgenically in another plant, but only in the context of a transgenic dicotyledonous plant such as tobacco. Dicotyledonous plants such as tobacco are far removed from transgenic corn. Besides the obvious seedling differences (single seed leaf vs. two seed leaf), dicots and corn are distinguished by numerous morphological, physiological and biochemical differences. For example, dicot cells respond to wounding in a manner quite different from corn cells. Wounded dicot cells react by proliferating, whereas wounded corn cells respond by dying. Dicots and corn differ in their mechanisms of photosynthetic carbon fixation and metabolism, reflected in morphological differences in, e.g., chloroplast type and function (mostly C3 plants in dicots vs. C4 plants in corn). Further, there are clear differences in codon usage between dicots and monocots. The foregoing differences are well recognized in the art of agricultural biotechnology, as evidenced by the textbook excerpts of Raven et al., Greulach et al. and Brimble et al. (Appendix A hereto).

The distinction between corn and dicots was a principal basis of the decision in *In re Goodman*, 29 U.S.P.Q. 2010 (Fed. Cir. 1993), where the Federal Circuit found that techniques applicable to

dicots were not applicable to monocots absent specific supporting evidence. Due to these significant biological differences alone, the disclosure of a gene functional in a dicot does not render *prima facie* obvious that gene in the context of transgenic corn. Most notably, the court noted that the “production of peptides in monocotyledonous plants involves extensive problems unaddressed by Goodman’s specification” which was found to be limited to dicotyledonous plants. 29 U.S.P.Q.2d at 2013.

**Genes Not Previously Expressed in Plants are even
Further Removed from the Claimed Transgenic Corn Species**

Transgenic corn engineered to express a gene not previously introduced transgenically into any plant and expressed, is still further removed from the prior art. The mere existence of a gene in a nontransgenic plant such as tobacco, soybean or corn, or its genetic engineering in a bacterium, cannot be said to provide a sufficient basis for a holding of obviousness. Where the gene is merely known to exist, the Examiner’s rejection can best be characterized as impermissible hindsight reconstruction, and fails to provide the requisite motivation. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988)

Claims 63, 64 and 66 are directed to transgenic corn bearing elements not previously genetically engineered into corn or, to Appellants’ knowledge, any other plant species. The genes specified in these claims have only been studied in non-transgenic plants, and in some cases engineered in bacterial systems, but have not, to Appellants’ knowledge, been expressed transgenically to provide a trait in plants.

Claim 64 is directed to transgenic corn bearing a PR protein gene. However, the exemplary reference, Bol et al. (Exh I), relates only to the induction of PR proteins in tobacco and says nothing about transgenic corn bearing a PR protein transgene.

In the case of claim 63, the references of Abe et al., Mundy et al. and Yenofsky et al. (Exhibit H) relate only to the cloning of an exemplary rice, barley, soybean or baculovirus gene in bacterial systems. O'Reilly et al. relates to the cloning of a baculovirus gene, and Dunn et al. merely describes the existence of DIMBOA on non-transgenic corn.

The same can be said for the transgenic corn species of claim 66.

***Vaeck* is Controlling**

Appellants submit that case of *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991), which is based upon very similar facts, is controlling. In *Vaeck*, the invention was directed to a gene encoding for insecticidal *Bacillus* proteins, and a method for expressing the gene in a cyanobacterium host. As here, in *Vaeck* the gene and its insecticidal activity was known in the prior art. The spores of the insecticidal *Bacillus* proteins were sprayed on swamps for the same purpose of killing insects. The prior art in *Vaeck* taught the expression of the gene for the same desirable activity in bacterial hosts. A secondary reference taught the expression of a gene encoding for the enzyme chloramphenicol acetyl transferase (CAT), in cyanobacteria. In *Vaeck*, both the host bacteria and cyanobacteria belonged to the prokaryote kingdom, and had similarities in their structures. Thus, the method of placing a gene, the CAT gene, and expressing the same in cyanobacteria was known. Based on this, the examiner in *Vaeck* argued that it would be *prima*

facie obvious to one skilled in the art to replace cyanobacteria for bacteria, or to replace the CAT gene for *Bacillus* gene.

The Federal Circuit reversed the holding of obviousness. One basis was the general unpredictability of the transgenic art, particularly with respect to cyanobacteria. More relevantly, though, the court found that there simply was no suggestion in the prior art to substitute the *Bacillus* gene for the CAT gene, even though the CAT gene was known to have desirable properties:

More particularly, there is no suggestion in ... the primary reference ... of substituting in the disclosed plasmid a structural gene encoding *Bacillus* insecticidal proteins for the CAT gene utilized for selection purposes.

20 U.S.P.Q.2d at 1443.

The court further held that the prior art did not suggest the substitution of the *Bacillus* gene into cyanobacterial host, emphasizing that simply because the gene was known to encode insecticidal activity was an insufficient basis to motivate one skilled in the art to place it in cyanobacteria:

While these references disclose expression of *Bacillus* gene encoding insecticidal proteins in certain transformed *bacterial* hosts, nowhere do these references disclose or suggest expression of such gene in transformed *cyanobacterial* hosts... none of these additional references disclose or suggest that cyanobacteria could serve as hosts for expression of genes encoding *Bacillus* insecticidal proteins. (emphasis in original)

20 U.S.P.Q.2d at 1443.

In the present case the genes and gene elements *per se* are known in prior art. Methods of placing exogenous DNA in fertile transgenic plants are also known. But, as in *Vaeck*, the expression of a gene in an unrelated plant does not render obvious the introduction and expression

of that gene in corn, without regard to whether there is available a technique that would be successful. As stated in § 103, “patentability shall not be negated by the manner in which the invention was made.” See also, *In re Kratz*, 201 U.S.P.Q. 71 (CCPA 1979).

The Answer posits that the motivation for such substitution is found *first*, in the fact that there is some inherent “desire to obtain the agronomic benefits for which each gene type is known.” But, as in *Vaeck*, the expression of a particular gene in one host to achieve a particular property does not motivate one of skill to express that gene in another species, and certainly provides no evidence that such an undertaking would be successful.

The *Vaeck* examiner also argued that since the CAT gene had been successfully expressed in cyanobacteria, this would have motivated one skilled in the art to express another gene in the same host. Although the method of accomplishing this was known, the court refused to find this to constitute a requisite suggestion to make the substitution.

In the present case, the Answer bases obviousness in part on the position that the specified genes had been previously isolated and expressed in different hosts, for example, transgenic tobacco plants, to induce the agronomically favorable traits. It is submitted that the Examiner is misconstruing the standards of obviousness required by *Vaeck*. There, the claimed genetic construct had been successfully expressed in host bacteria, but had not been expressed in host cyanobacteria for the specified benefits. And, despite the known amino acid sequence homology between bacteria and cyanobacteria, the court pointed out that the prior art also disclosed various differences between the two hosts; therefore, the substitution of hosts was not obvious. Similarly here, the fact that the same genes were expressed in tobacco for same benefits, without more,

does not make obvious the introduction of these genes in a different host; namely, fertile transgenic corn plant. *In fact, here there is very little similarity between dicots such as tobacco and corn plants to motivate those skilled in the art to even attempt the substitution.*

***Deuel* Also Supports a Conclusion of Nonobviousness**

The Answer has attempted to distinguish *In re Deuel*, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995), stating that in *Deuel* the prior art taught only a method and not DNA *per se*, whereas in the present case, the subject DNA and the transgenic method of introducing the DNA into corn was known.

The rejection in the present case is no different from that in *Deuel*, where the amino acid coding sequence of the claimed gene was known generically based on the known correlation between amino acid and DNA sequence. Yet because the prior art did not specifically disclose the particular gene sequence claimed, the claimed gene was non-obvious:

Further, while the general idea of the claimed molecules, their function, and their general chemical nature may have been obvious from Bohlen's teachings, and the knowledge that some gene existed may have been clear, the precise cDNA molecules of claims 5 and 7 would not have been obvious over Bohlen because Bohlen teaches proteins, not the claimed closely related cDNA molecules.

34 U.S.P.Q.2d at 1215.

Similarly, here, the prior art does not teach the *specific* combination of the claims, it only teaches some other plant or organism or a non-transgenic plant bearing the gene. Furthermore, *Deuel* approved of the principle that if prior art teaches a specific, structurally-definable compound, then the question becomes whether the prior art would have suggested making the

specific molecular modifications necessary to achieve the claimed invention. The fertile transgenic corn plant of Lundquist and of the present invention differ structurally in that the particular molecular modifications in the claimed plant resulting from the insertion of the claimed groupings of genes and gene elements would render the claimed corn plant a chemical entity different from, and nonobvious over, that which existed in prior art.

To define the claimed invention as the Examiner did, in the terms that the prior art and the claimed invention differ, “in the precise recitation of the DNA of interest” is to ignore the importance of improvements in furthering science and technology, the enhancement of which underlies the policy of patent law.

In that Appellants’ claims are directed to a new chemical entity in structural terms, a *prima facie* case of unpatentability requires that the teachings of the prior art suggest *the specific claimed compound* to a person of ordinary skill in the art. Even if the *general idea* of the claimed compound, their function, and their general chemical nature, may have been obvious from the teachings of the prior art, and the knowledge that some genes existed may have been clear, the particular combination claimed is not obvious, for the same is not disclosed, either explicitly or implicitly, in any of the prior art references cited. Until the claimed combination of particular genes and gene elements was disclosed in the present application, it was unlikely that one of ordinary skill in the art would have contemplated what was ultimately obtained by the appellants. “What cannot be contemplated or conceived cannot be obvious.” *Id.*

To support the holding in *Deuel* that “what cannot be conceived cannot be obvious,” Appellants refer to the decision in *Amgen Inc., v. Chugai Pharmaceutical Co. Ltd.*, 18 U.S.P.Q.

1016 (Fed. Cir. 1991), where the court defined the meaning of ‘conception’ of a chemical compound. The court said that such conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define the compound so as to distinguish it from other materials . It is not sufficient to define it solely by means of its biological property, because *an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property*. Similarly, the reference in Lundquist *et al.* to any and all type of DNA which provides for the biological traits desired for said corn plant is simply a wish to know the identity of a specific chemical composition with that biological property . Lundquist *et al.* merely teaches the general method but not the combination that is specifically claimed.

The Answer further takes the position that some of the particular traits recited in Lundquist are the same as the traits sought to be achieved with the albeit distinct genes set forth in the appealed claims, and that reference is made generally in Lundquist to the introduction of “all DNA” which provides for, or enhances, a beneficial feature of the resultant transgenic corn plant. But, *Deuel* stands for the proposition that, “A *general* incentive does not make obvious a *particular* result, nor does the existence of techniques [in prior art] by which those efforts can be carried out” (emphasis added) ... “The fact that one can conceive a general process in advance for preparing an *undefined* compound does not mean that a claimed *specific* compound was precisely envisioned and therefore obvious.” 34 U.S.P.Q.2d at 1216. In the present case, all Lundquist *et al.* teaches is a generic compound that may have all the useful DNA to achieve agronomic benefits. The particular combination and grouping that DNA set forth in the appealed claims has nowhere been disclosed.

**An Earlier "Generic" Teaching, such as Lundquist, does not
Render *prima facie* Obvious a Later Species within that Genus**

Appellants would refer the Board to *In re Jones*, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992), again to point out the *Genus-Species* relation between Lundquist *et al.* and the present invention.

In *Jones*, the claimed invention was directed to a salt of an acid called dicamba. Dicamba was a known herbicide. Among the various salt forms disclosed in the prior art were the ammonium salts, which formed the genus that admittedly encompassed the claimed salt. The prior art salt and the claimed salts also had a common utility, *i.e.*, herbicidal utility. The Solicitor argued that since the prior art disclosed the genus and, since the salts of dicamba were known for their herbicidal activity, one skilled in the art would have motivation to use with dicamba, substituted ammonium salts made from a known amine, and would expect such a salt to have the same herbicidal activity.

The court rejected this view, and found the differences in the structure of the claimed salts and prior art salts were non-obvious, *even though both had the same beneficial property*. The fact that the claimed salt was a member of a broadly claimed genus of substituted ammonium salts of dicamba in a prior art reference, did not, in the court's view, render the specific claimed species of the salt obvious. "Though (prior art) discloses the potentially infinite genus of 'substituted ammonium salts' of dicamba, and lists several such salts, the salt claimed here is not specifically disclosed." The fact that prior art salts had a beneficial property that may be enough to motivate one skilled in the art to make more salt forms of the same acid for same purposes, did not convince the court that the claimed invention should be held obvious for that reason.

Similarly in the present case, the prior art reference Lundquist *et al.* discloses potentially *infinite genus* in terms such as “all DNA,” the prior art also gives a general guidance to one skilled in the art by disclosing the various traits desirable for the corn plant. The prior art also discloses certain genes that code for the specific traits mentioned therein. The prior art therefore, presumably, encompasses the claimed combination; but, the prior art does not specifically disclose the particular combination of genes and gene elements in the transgenic corn plant as claimed. The fact that the genes disclosed in Lundquist *et al.* and the genes used in the claimed combination have common utility is also of no consequence in view of the holding of *In re Jones, supra*. In *In re Jones, supra*, the prior art salt and the claimed salt also had common herbicidal utility. Therefore, even if the genes of the present invention are known for their traits, and the genes disclosed in prior art, and those used in the claimed combination have common beneficial effects, that alone, without more, cannot render the claimed invention obvious.

To reject the present claims because Lundquist *et al.* discloses or refers to use of “all DNA,” amounts to doing away with the principle that was very carefully developed in the patent law; namely, that, ‘a claim to a particular species is patentable over the disclosed genus (that is infinite and undefined).’ *Jones*, see also April 17, 1995 Commissioner’s Notice to Examiners, agreeing that *Baird* was good law. 50 PTCJ 3 (May 4, 1995). Moreover, it is not the position of the Examiner that the genes used in the claimed combination are structurally similar to those disclosed in Lundquist *et al.*, or that after augmenting the genome of a fertile transgenic plant, the plant would be structurally similar to a fertile transgenic plant transformed with genes disclosed in Lundquist *et al.* or Goldman *et al.*

3. Conclusion

Appellants submit that the issues raised in the Answer with respect to obviousness have been fully addressed in the main Brief and the foregoing Reply. It is submitted that Appellants' have fully demonstrated that the Examiner has failed to make a *prima facie* case of obviousness, based upon a consideration of the prior art and the prevailing case law.

B. Rejection of Claim 50 under 35 U.S.C. § 112, Second Paragraph

The Examiner has introduced a rejection of claim 50, on the basis that it is depends from a rejected base claim.

Claim 50 was canceled on the basis that there was no pending claim having an appropriate antecedent basis ("replication vector") for this claim. Thus, this rejection is now moot.

C. Summary and Conclusion

In light of the foregoing comments, appellants submit that the appealed claims meet the requirements for patentability. Therefore, appellants respectfully request that the Board reverse each of the rejections.

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